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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,349	07/23/2004	Ali Rezai	12637/71	6084
23838 7590 04/19/2007 KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER DIETRICH, JOSEPH M	
			ART UNIT 3709	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/502,349	REZAI ET AL.	
	Examiner	Art Unit	
	Joseph M. Dietrich	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed July 23, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

In order for "Deep Brain Stimulation for Chronic Pain" in Surgical Management of Pain to be considered, a legible copy of the chapter must be included.

Claim Objections

2. Claim 19 is objected to because of the following informalities: "Nigra" is spelled incorrectly on line 7 of claim 19. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 provides for the use of a stimulator, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant

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is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 39 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1 - 36 rejected under 35 U.S.C. 103(a) as being unpatentable over King (U.S. Patent 5,713,922).

Regarding claims 1 – 36, King discloses a method of affecting chronic pain in a patient comprising: a) implanting a stimulator (22A) in a target site of the brain; and b) providing a stimulation signal to the stimulator to stimulate the target site to affect chronic pain (column 3, lines 58 – 65). King does not disclose that the target site is selected from the group consisting of the pre-frontal cortex, orbitofrontal cortex, anterior limb of the internal capsule, insular cortex, primary somatosensory cortex, secondary somatosensory cortex, cingulate cortex, anterior cingulate cortex, and posterior cingulate cortex, inferior frontal gyrus, middle frontal gyrus, superior frontal gyrus, medial frontal gyrus, parahippocampal gyrus, precuneus, amygdala, and hippocampus or consisting of the anterior nucleus of the thalamus, intralaminar thalamic nuclei, dorsomedial nucleus of the thalamus, mammillary body, lateral hypothalamus, locus coeruleus, dorsal raphe nucleus, substantia nigra pars compacta, substantia nigra pars reticulata, superior colliculus, tegmentum, tectum, medial thalamus, nucleus accumbens, ventral striatum, and ventral pallidum. However, King does disclose that

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deep brain stimulations is done to excite particular neural tissue elements of the thalamus, globus pallidus and other nuclear groups for the relief of chronic pain (column 4, lines 32 – 34). King also discloses the locus of excitation could be shifted along the lead (column 4, lines 28 – 29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King to include all the desired target sites, instead of just disclosing “other nuclear groups” (column 4, line 33), in order promote the relief of chronic pain.

10. Claims 1 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over King (U.S. Patent 5,713, 922) in view of Brown (“Motor Cortex Stimulation,” Neurosurgical Focus (Sep 15, 2001) 11(3): E5).

Regarding claims 1 – 18, Brown discloses that stimulation of the prefrontal cortex can provide pain relief (page 2, paragraph 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King to include stimulation to the prefrontal cortex in order to relieve chronic pain. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King to include stimulation not only to the prefrontal cortex, but also to the other areas included as cerebral targets.

Regarding claims 19 – 36, Brown discloses that electrical stimulation of the thalamus can treat central pain syndromes (page 1, paragraph 4) and both the post- and precentral gyri are involved in pain (page 1, paragraph 2).

It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify King to include stimulation to the thalamus and to the post and precentral gyri in order to relieve chronic pain. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King to include stimulation not only to the thalamus and the post and precentral gyri, but also to the other areas included as deep brain targets.

11. Claims 1 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff (U.S. Patent 5,938,688).

Regarding claim 19 and 21, Schiff discloses a method of affecting chronic pain in a patient comprising: a) implanting a stimulator in a target site of the brain; and b) providing stimulation to the stimulator to stimulate the target site to affect chronic pain, the target site selected from the group consisting of the anterior nucleus of the thalamus, intralaminar thalamic nuclei, dorsomedial nucleus of the thalamus, mammillary body, lateral hypothalamus, locus coeruleus, dorsal raphe nucleus, substantia nigra pars compacta, substantia nigra pars reticulata, superior colliculus, tegmentum, tectum, medial thalamus, nucleus accumbens, ventral striatum, and ventral pallidum and wherein the target site is the intralaminar thalamic nuclei (column 4, lines 61 – 66 and column 5, lines 34 – 46). Although Schiff discloses that this method is preferably for treating conscious patients having impaired cognitive function (column 1, lines 10 – 12), Schiff later discloses that the patient may suffer from a variety of other ailments in addition to impaired cognitive function, including chronic pain (column 2, lines 36 – 40).

It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify Schiff so that only chronic pain was being affected by the method taught.

Regarding claims 1 – 18, 20, and 22 – 36, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include electrical stimulation and/or pharmacological agent delivery to other cerebral and deep brain target sites throughout the brain in order to affect chronic pain.

12. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over King or Schiff in view of Budai et al. ("Endogenous Opioid Peptides Acting at μ -Opioid Receptors in the Dorsal Horn Contribute to Midbrain Modulation of Spinal Nociceptive Neurons," *Journal of Neurophysiology* (1998) 79(2): 677 – 687). Both King and Schiff disclose a method of affecting chronic pain comprising: a) implanting a stimulator in communication with a pain circuitry target site. Neither discloses providing as stimulation signal to the stimulator to stimulate the synthesis or release of an endogenous opioid to affect chronic pain. However, Budai discloses that the inhibition of nociceptive neurons is mediated in part through the local release of an endogenous opioid acting at the μ opioid receptor (page 683, paragraph 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King or Schiff to include the stimulating the synthesis or release of an endogenous opioid to affect chronic pain as taught by Dubai.

13. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over King or Schiff in view of Rise et al. (U.S. Patent 6,109,269). Both King and Schiff disclose a method of affecting chronic pain comprising: a) implanting a stimulator in

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communication with a pain circuitry target site; and d) stimulating the target site to affect the hypothalamic-related condition. Neither discloses b) detecting a bodily activity of the body associated with the chronic pain; or c) providing a stimulation signal to the stimulator in response to the detected bodily activity. However, Rise discloses detecting a bodily activity of the body (column 9, lines 50 – 52); and providing a stimulation signal to the stimulator in response to the detected bodily activity (column 9, lines 53 – 59).

The method taught by Rise is not used to affect chronic pain; it is, however, used to deliver stimulation (in the form of either electrical pulses or drug delivery) to target sites within the brain. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King or Schiff to include a sensor that could detect bodily activity and could communicate with either the pulse generator or drug pump to deliver stimulation based on the bodily activity as disclosed by Rise.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. This prior art consists of: King et al. (U.S. Patent 5,925,070), Crain et al. (U.S. Patent 6,096,756), and Cesselin, F. ("Opioid and anti-opioid peptides," *Fundamentals and Clinical Pharmacology* (1995) 9(5): 409-33 (ABSTRACT ONLY)).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is 571-270-1895. The examiner can normally be reached on Mon - Fri, 8:00AM - 5:00PM, Alt Fri, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD

JMD

March 28, 2007

GARY JACKSON
SUPERVISORY PATENT EXAMINER

Gary Jackson
4-16-2007